



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,179	07/11/2001	Dan K. Ahlgren	5510US	1180
30328	7590	07/14/2004	EXAMINER	
NU VASIVE, INC. 10065 OLD GROVE ROAD SAN DIEGO, CA 92131			RAMANA, ANURADHA	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/904,179

Applicant(s)

AHLGREN, DAN K.

Examiner

Anu Ramana

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-12, 14-21 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2, 3, 6-8, 18 and 19 is/are allowed.
- 6) ☒ Claim(s) 4, 5, 9-12, 14-17, 20, 21 and 23-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3732

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 5, 11, 17 and 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Brantigan (US 5,192,327).

Brantigan discloses an implant or prosthesis or “an intervertebral support system” 10 with a center portion having top and bottom recesses facing cranially and caudally, a top portion having bottom recesses facing caudally, and a bottom portion having top recesses facing cranially wherein the top and bottom portions are interchangeable and each of the top, center and bottom portions is made of an inert metal (Figures 4 and 14, col. 4, lines 1-19, col. 5, lines 30-34 and col. 7, lines 1-3).

Regarding claim 23, it is noted that Brantigan discloses a tool having two prongs to support each of the top, bottom and center portions (see Fig. 14). With regard to the side grooves being “dimensioned to receive one of the two prongs therein,” it has been held that the recitation that an element is adapted to perform a function is not a positive limitation but only requires the ability to so perform and does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Regarding claim 25, Brantigan discloses each portion to have end faces 11c with ridges having inclined or tapered walls or ramp surfaces 12a (col. 4, lines 15-19).

The method steps of claims 17, 23 and 24 are inherently performed during assembly and insertion of the Brantigan intervertebral support system between adjacent vertebrae.

Art Unit: 3732

Claims 4, 9 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Cohen et al. (US 6,454,806).

Cohen et al. disclose an implant or prosthesis or intervertebral support system 1B having a center portion 44 having top and bottom recesses facing cranially and caudally, a top portion 2B having recesses facing caudally, and a bottom portion 3B having recesses facing cranially (Figure 6, col. 1, lines 4-8, col. 8, lines 62-67 and col. 9, lines 1-9).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (US 5,192,327).

Regarding claims 12 and 14-16, it would have been an obvious matter of design choice to have dimensioned implant 10 with a size less than 6 mm or a size less than 8 mm, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Regarding claim 15, Brantigan discloses that the intervertebral implant can be made of a biologically acceptable material. Although Brantigan does not specifically disclose that the intervertebral implant is made of bone allograft, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the implant of bone allograft, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, herein biocompatibility, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Art Unit: 3732

Regarding claim 16, Brantigan discloses that the intervertebral implant is made of an inert metal (col. 4, lines 1-5).

Alternatively, claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (US 5,192,327) in view of Nicholson et al. (US 6,241,769).

Brantigan does not disclose that the vertebral implant is made from bone allograft.

Nicholson et al. teach that bone allograft material can be used to fabricate implants to match the elastic properties of a patient's bone (col. 4, lines 9-13).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized bone allograft as taught by Nicholson et al. for the purpose of fabricating the Brantigan implant to match the elastic properties of a patient's bone.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (US 5,192,327), as applied to claim 17, further in view of Zucherman et al. (US 6,048,342).

Brantigan discloses all elements of the claimed invention except for insertion of implants through a cannula.

Zucherman et al. teach minimally invasive insertion of implants through a cannula (col. 1, lines 23-26 and col. 11, lines 14-38).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized a cannula, as taught by Zucherman et al., for deposition of the Brantigan implant.

Further, it would have been an obvious matter of design choice to have utilized a cannula having an interior diameter of at least 6 mm, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

The method steps of claims 20 and 21 are rendered obvious by the combination of Brantigan and Zucherman et al.

Art Unit: 3732

Response to Arguments

Applicant's arguments submitted under "REMARKS" in the response filed on April 2, 2004 have been considered but are not persuasive with respect to claims.

With respect to the rejection of claim 5 under 35 U.S.C 102(b), regarding the side grooves being "adapted to receive a prong of a positioning tool therein," it has been held that the recitation that an element is adapted to perform a function is not a positive limitation but only requires the ability to so perform and does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

With respect to claims 11, 17, 26 and 27, it is the Examiner's position that Brantigan discloses top, center and bottom portions having a "generally elongate shape," i.e., having more length than width (see Fig. 1).

Applicant's arguments with respect to the rejections of claims 4, 9 and 10 under 35 U.S.C 102(b) by Cohen et al. are not persuasive for the following reason. Further, Applicant's arguments are directed to unclaimed features.

Fig. 6 of Cohen et al. clearly shows the center portion 44 to have an end or "extremity" with a downward taper from a top surface and an upward taper from a bottom surface. See Attachment A for a marked up Figure 6 from Cohen et al.

Allowable Subject Matter

Claims 2,3,6,7, 8, 18 and 19 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 3732

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Anu Ramana*
July 9, 2004

Kevin Shaver
KEVIN SHAVER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

ATTACHMENT A

